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Dockets Management Branch (HFA-305)
Food and Drug Admin.
5630 Fishers Lane, Rm 1061
Rockville, MD 20852

[Docket No. 99N-0391]

Topic 1. If the CCNFSDU does not intend that the paper consider the addition of vitamins and minerals to conventional foods nor products containing other ingredients or substances, then the terminology should be restricted to "vitamin and mineral supplements." Probably no need for this topic.

Topic 2. Should be deleted as the subject is too broad. There are doses to maintain health and therapeutic doses that vary with each individual.

Topic 3. There should be nothing on the negative list for vitamins and the only minerals that should be on the list are those known to cause serious injury, such as arsenic, cadmium, and lead. Other minerals can be toxic in larger quantities than recommended, i.e. selenium. A small amount is vital.

Topic 4. The maximum levels should depend on the GRAS level. A notation on the label "Doses above the GRAS level should be taken only on the advice of a health care professional."

Care should be taken not to restrict vitamins. There is continuing change (advancement) in maximum doses of certain vitamins. Example 1: Vit C; RDA 60 mg; most health care professionals recommend 1500-2500 mg; Dr. Linus Pauling took 10,000 mg for years and lived to be 91 years of age. Example 2: A young healthy person may get all the Vit D3 (calciferol) they need by being out in the sun for 15 min's/day, while an elderly person that cannot get the vit D needed from the sun may need 5000I.U./day. A person with serious osteoporosis may need 25,000I.U./day.

Maximum levels should be ascertained by a group of scientists that are experienced in vitamins and minerals, but not the AMA or scientists that have conflicting interest of the pharmaceutical industry. Probably the best source of this information would be M.D.'s and other health care professionals that actually have experience with nutritional support for degenerative diseases.

Topic 5. There could be a minimum level in order for the supplement to listed on the label, but no other minimum restriction. Topic could be deleted.

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Topic 6. There should be regulations on purity and good manufacturing practices. A person taking an imported product should have some reason to expect that the product will not do harm from impurities especially pesticides and deadly bacteria.

In order for a manufacturer to get an export license, they should be inspected. An independent group could inspect these exporters once every five (5) years to maintain their licenses.

Topic 7. Manufacturers should be able to indicate on the label the most common use for the product. Other uses could be left up to the manufacturer also.

A warning on the label "Do not exceed the recommended dose unless under the advice of a health care professional."

A warning for some supplements that could be detrimental to pregnant, lactating women and children should also be on the label.

Sincerely,

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